K133317

MAY 13 2014

1 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the Penumbra System® / Penumbra System® MAX components.

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

1.2 Sponsor Contact Information

Seth Schulman
Director, Regulatory Affairs
Phone: (510) 748-3223
FAX: (510) 217-6414
Email: seth.schulman@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 13, 2014

1.4 Device Trade or Proprietary Name

Penumbra System® / Penumbra System® MAX

1.5 Device Classification

Regulatory Class:	II
Review Panel:	Neurology
Regulation Name:	Catheter, Thrombus Removal
Regulation Number:	21 CFR §870.1250
Product Code:	NRY

1.6 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K072718 [28Dec2007]	Penumbra System [026, 032, 041]	Penumbra, Inc.
K090752 [21Sep2009]	Penumbra System [054]	Penumbra, Inc.
K100769 [21May2010]	Penumbra System Separator Flex [026, 032, 041, 054]	Penumbra, Inc.
K113163 [28NOV2011]	Penumbra System® MAX	Penumbra, Inc.

1.7 Device Description

The purpose of this 510(k) pre-market notification is to implement the following modifications to the Instructions for Use for clarity.

- Added Summary of PIVITOL Trial Clinical Data
- Moved a precaution statement to the Warnings section
- Added statement that the use of a Separator may not be needed for Reperfusion Catheters with an I.D. of 0.054in or larger.

1.8 Intended Use

The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

1.9 Summary of Non-Clinical Data

The following non-clinical testing was performed to support the proposed wording clarifications in the Instructions for Use.

Test	Test Method Summary	Result
Catheter Tip Pressure	Aspiration (Suction) pressure was measured at the distal tip of the Reperfusion catheters (All Sizes).	The aspiration pressure at the distal tip of the Reperfusion Catheters was equal to the pressure set at the Pump.
Aspiration Flow Rate	The flow rate through the Reperfusion Catheter was measured with and without Separators present in the catheter lumen. (054, 5MAX & 5MAX ACE)	The flow rate was consistently higher without the presence of the Separator in Lumen.
Clot Removal Simulated Use	Clot was removed from a glass model under - 20 inHg vacuum (without Separator). (054, 5MAX & 5MAX ACE)	All Reperfusion Catheters were able to completely remove the clot without the use of a Separator.

1.10 Summary of Substantial Equivalence

The Penumbra System MAX components are substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Penumbra, Inc.
Mr. Seth Schulman
Director, Regulatory Affairs
1352 Harbor Bay Parkway
Alameda, CA 94502

Re: K133317
Trade/Device Name: Penumbra System and Penumbra System MAX
Regulation Number: 21 CFR 870.1250
Regulation Name: Thrombus Removal Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 7, 2014
Received: April 8, 2014

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133317

Device Name
Penumbra System / Penumbra System MAX

Indications for Use *(Describe)*
The Penumbra System / Penumbra System MAX are intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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